

1 I CLAIM:

- 2 1. A method for delivering a medicine to a  
3 patient's respiratory system, comprising:  
4 positioning an endotracheal tube in the  
5 patient's respiratory system;  
6 positioning a nebulization catheter in the  
7 patient's respiratory system; and  
( 8 operating the nebulization catheter to produce  
9 an aerosol of the medicine at a distal end of the  
10 nebulization catheter while the endotracheal tube is  
11 positioned in the patient's respiratory system.
- 12 2. The method of Claim 1 in which the step of  
13 operating the nebulization catheter further comprises:  
14 delivering a liquid medicine to a first orifice  
15 located at the distal end of the nebulization catheter;  
16 and  
17 delivering a pressurized gas to a second  
18 orifice located at the distal end of the nebulization  
19 catheter in proximity to the first orifice to aerosolize  
20 the liquid medicine at the first orifice.
- 21 3. The method of Claim 1 in which the step of  
22 operating the nebulization catheter further comprises:  
23 connecting a pressurized canister containing a  
24 mixture of a medicine and a liquid propellant to a  
25 proximal end of the nebulization catheter;  
26 delivering the mixture of medicine and liquid  
27 propellant through a first lumen of the nebulization  
28 catheter to a first distal orifice located at the distal  
29 end of the nebulization catheter; and  
30 delivering a pressurized gas through a second  
31 lumen of the nebulization catheter to a second orifice  
32 located at the distal end of the nebulization catheter in  
33 proximity to the first orifice to enhance the  
34 aerosolization of the medicine emitted from the first  
35 orifice.

1                   4. The method of Claim 3 in which the  
2                   pressurized gas from the second orifice is directed  
3                   against the medicine and propellant delivered from the  
4                   first distal orifice.

5                   5. The method of Claim 1 further comprising:  
6                   centering the nebulization catheter in the  
7                   endotracheal tube.

8                   6. The method of Claim 1 in which the step of  
9                   positioning a nebulization catheter further comprises:  
10                  positioning a nebulization catheter through an  
11                  auxiliary lumen of the endotracheal tube.

12                  7. The method of Claim 1 further comprising:  
13                  removing the nebulization catheter while  
14                  leaving the endotracheal tube in position in the  
15                  patient's respiratory system.

16                  8. The method of Claim 2 further comprising  
17                  the step of:  
18                  imparting pulsation to the liquid being  
19                  delivered.

20                  9. The method of Claim 8 in which the  
21                  pulsation is imparted at a frequency greater than 100  
22                  hertz.

23                  10. The method of Claim 8 in which the  
24                  pulsation is applied to a proximal reservoir from which  
25                  the liquid medicine is supplied.

26                  11. The method of Claim 8 in which the  
27                  pulsation is associated with the delivery of less than  
28                  approximately 10 microliters of liquid medicine.

1                   12. The method of Claim 1 in which the step of  
2                   operating a nebulization catheter further comprises the  
3                   step of:

4                   applying an electric signal to the distal end  
5                   of the nebulization catheter to produce the aerosol from  
6                   said distal end.

7                   13. The method of Claim 1 further comprising:  
8                   providing a coaxial airflow to said distal end  
9                   of said nebulization catheter to constrain aerosol  
10                  therefrom.

11                  14. The method of Claim 1 further comprising:  
12                  providing humidification to the patient's  
13                  respiratory system.

14                  15. The method of Claim 1 further comprising  
15                  the step of:  
16                  balancing airflow at the distal end of the  
17                  nebulization catheter by withdrawing air through a vacuum  
18                  lumen extending through the nebulization catheter.

19                  16. The method of Claim 1 in which the step of  
20                  positioning the nebulization catheter further comprises:  
21                  receiving an indication of the position of the  
22                  nebulization catheter relative to the endotracheal tube.

23                  17. The method of Claim 16 in which the  
24                  indication is a tactile indication.

25                  18. The method of Claim 16 in which the step  
26                  of receiving an indication further comprises:  
27                  receiving a indication of a pressure variation  
28                  at a distal end of the endotracheal tube as the distal  
29                  end of the nebulization catheter is moved past.

1                   19. A method for delivering a medicine to one  
2 or both lungs of a patient who is not intubated,  
3 comprising:

4                   positioning a nebulization catheter in the  
5 patient's respiratory system; and

6                   operating the nebulization catheter to produce  
7 an aerosol of the medicine at a distal end of the  
8 nebulization catheter.

9                   20. A method of delivering an aerosol of  
10 medication to a patient's lungs, comprising:

11                   nebulizing the medication at a distal end of a  
12 catheter located in the patient's respiratory tract, said  
13 distal end of said catheter directed in a first  
14 direction; and

15                   directing a flow of gas at said nebulized  
16 medication in a direction opposite to said first  
17 direction.

18                   21. The method of Claim 20 in which said first  
19 direction in said nebulizing step is a distal direction.

20                   22. The method of Claim 20 in which said first  
21 direction in said nebulizing step is a proximal  
22 direction.

23                   23. The method of Claim 20 in which said  
24 directing step is further characterized by:

25                   directing a flow of gas from a distal end of an  
26 endotracheal tube.

27                   24. The method of Claim 20 in which said flow  
28 of gas is an inhalation of the patient through an  
29 endotracheal tube.

1                   25. A method of delivering a medicine  
2 selectively to a bifurcated region of a patient's  
3 respiratory system, comprising:  
4                   positioning a catheter into a branch of the  
5 patient's respiratory system that leads to a region other  
6 than the region to which the medicine is to be delivered;  
7                   delivering an airflow through the catheter; and  
8                   nebulizing the medicine in the respiratory  
9 system proximal of where the airflow is delivered whereby  
10 a plume of the nebulized medicine is delivered to the  
11 region without the catheter.

12                   26. A catheter for delivering an aerosol of  
13 medicine to a patient's lungs comprising:  
14                   a catheter shaft having a proximal end and a  
15 distal end;  
16                   a lumen through the catheter shaft and  
17 communicating at the proximal end with a port for  
18 receiving a medicine in a liquid form and communicating  
19 at the distal end with a distal orifice from which the  
20 medicine can be discharged;  
21                   means for nebulizing the medicine discharged at  
22 the distal orifice into an aerosol plume of particles of  
23 the medicine; and  
24                   means for modifying the aerosol plume of  
25 particles of medicine.

26                   27. The catheter of Claim 26 wherein the  
27 modifying means comprises:  
28                   a vacuum orifice located close to the distal  
29 orifice from which the medicine is discharged for  
30 scavenging air from the nebulized aerosol.

31                   28. The catheter of Claim 26 wherein the  
32 modifying means comprises:  
33                   means for decreasing the velocity of the  
34 particles.

1                   29. The catheter of Claim 26 wherein the  
2     modifying means comprises:  
3                   means for increasing the width of the aerosol  
4     plume .

5                   30. A catheter system for delivering an  
6     aerosol of medicine to a patient's lungs comprising:  
7                   a catheter shaft having a proximal end and a  
8     distal end;  
9                   a lumen through the catheter shaft and  
10    communicating at the proximal end with a port for  
11    receiving a medicine in a liquid form and communicating  
12    at the distal end with a distal orifice from which the  
13    medicine can be discharged;  
14                   means for nebulizing the medicine discharged at  
15    the distal orifice;  
16                   a flow control apparatus connected to the port,  
17    said flow control apparatus comprising:  
18                   a flow line communicating with the port, said flow  
19    line occupied by the medicine; and  
20                   a valve associated with the flow line to cause  
21    pulsed delivery of medicine through the flow line.

22                   31. The catheter system of Claim 30 in which  
23    said flow control apparatus further comprises:  
24                   a draw back area associated with the flow line,  
25    said draw back area adapted to cause a reversal of flow  
26    of medicine through the flow line controller synchronized  
27    with the pulsed delivery.

28                   32. A catheter for delivering an aerosol to a  
29    patient's lungs comprising:  
30                   a shaft comprised of:  
31                   an outer tubular member defining a first lumen  
32    and terminating at a distal end in a first distal  
33    orifice;

1           an inner tubular member defining a second  
2 lumen, said inner tubular member located in the first  
3 lumen and terminating at a distal end in a second distal  
4 orifice;

5           a manifold connected to a proximal portion of said  
6 shaft, said manifold having:

7           a first port communicating with the first lumen  
8 for conveyance of a pressurized gas in an annular region  
9 between the inner and outer tubular members; and

10           a second port communicating with the second  
11 lumen for conveyance of a medicine;  
12 said second distal orifice aligned with said first distal  
13 orifice to nebulize the medicine from a distal tip of the  
14 catheter.

15           33. The catheter of Claim 32 further  
16 comprising:

17           a retractable pin located in said second lumen.

18           34. A catheter for delivering an aerosol of  
19 medicine to a patient's lungs comprising:

20           a catheter shaft having:

21           a first lumen centrally located in said shaft  
22 and adapted for conveying a medicine in liquid form;

23           a plurality of lumens peripherally located  
24 around said first lumen and adapted for conveying a gas;

25           a distal liquid orifice communicating with said  
26 first lumen; and

27           a plurality of distal gas orifices  
28 communicating with said plurality of lumens, said  
29 plurality of distal gas orifices aligned with respect to  
30 said distal liquid orifice so as to nebulize a liquid  
31 medicine discharged from the liquid orifice.

32           35. A catheter system for delivering an  
33 aerosol therapy to a patient's lungs comprising:

1           a stand-alone nebulization catheter having a  
2           distal end for insertion into the respiratory system of a  
3           patient and a proximal end, said nebulization catheter  
4           having:

5                 a catheter shaft;

6                 a gas pressurization lumen extending through  
7           said catheter shaft;

8                 a distal gas exit orifice communicating with  
9           said gas pressurization lumen, said distal gas exit  
10          orifice located at the distal end of said nebulization  
11          catheter;

12                a drug delivery lumen extending along at least  
13          a portion of said catheter shaft; and

14                a distal drug delivery orifice communicating  
15          with said drug delivery channel, said distal drug  
16          delivery orifice located in proximity to the distal gas  
17          exit orifice so that gas exiting from said distal gas  
18          exit orifice nebulizes a drug delivered from said distal  
19          drug delivery orifice.

20                        36. The catheter system of Claim 35 further  
21          comprising:

22                        an endotracheal tube having a ventilation lumen  
23          in which said nebulization catheter extends.

24                        37. The catheter system of Claim 35 further  
25          comprising:

26                        an endotracheal tube having a ventilation lumen  
27          and an auxiliary lumen located adjacent to said  
28          ventilation lumen, said auxiliary lumen having a distal  
29          aperture into said ventilation lumen such that a distal  
30          end of said auxiliary lumen exits into the ventilation  
31          lumen close to a distal end thereof, and further in which  
32          said nebulization catheter extends through said auxiliary  
33          lumen.



1                   38. The catheter system of Claim 35 further  
2 comprising:  
3                   a centering apparatus located on said catheter  
4 shaft close to the distal end.

5                   39. The catheter system of Claim 35 in which  
6 the centering apparatus has an expanded size and a  
7 reduced size and the centering device assumes the  
8 expanded size when deployed in an airway passage.

9                   40. The catheter system of Claim 35 in which  
10 the centering apparatus includes more than one expanded  
11 size.

12                   41. The catheter system of Claim 35 in which  
13 the centering apparatus has an expanded size that can be  
14 adjusted after deployment.

15                   42. The catheter system of Claim 35 in which  
16 said centering apparatus comprises gas centering jets.

17                   43. The catheter system of Claim 35 in which  
18 the nebulization catheter includes a valve located in at  
19 least one of the lumens.

20                   44. The catheter system of Claim 43 in which  
21 the valve is located in at least one of the distal  
22 orifices.

23                   45. The catheter system of Claim 43 in which  
24 the valve is controlled from the proximal end of the  
25 nebulization catheter.

26                   46. The catheter system of Claim 43 in which  
27 the valve is actuated from the distal end of the  
28 catheter.

1                   47. The catheter system of Claim 43 in which  
2 the valve is formed by an elastically closed tip.

3                   48. The catheter system of Claim 35 further  
4 comprising a safety stop on a proximal portion of the  
5 catheter shaft.

6                   49. The catheter system of Claim 35 further  
7 comprising:  
8 graduated markings on said catheter shaft.

9                   50. The catheter system of Claim 35 further  
10 comprising:  
11 luer lock connectors on proximal ports  
12 communicating with said gas pressurization lumen and said  
13 drug delivery lumen.

14                   51. The catheter system of Claim 35 further  
15 comprising:  
16 self-sealing proximal ports communicating with  
17 said gas pressurization lumen and said drug delivery  
18 lumen.

19                   52. The catheter system of Claim 35 further  
20 comprising:  
21 means for clearing flow blockages at the distal  
22 end of the catheter.

23                   53. The catheter system of Claim 35 further  
24 comprising:  
25 a retractable pin located in at least one of  
26 said lumens.

27                   54. The catheter system of Claim 35 further  
28 comprising:  
29 a stripe on said catheter shaft.

1                   55. The catheter system of Claim 35 further  
2 comprising:

3                   a baffle located at the distal end of the  
4 nebulization catheter in front of the orifices.

5                   56. The catheter system of Claim 35 in which  
6 said catheter shaft includes a third lumen extending  
7 therethrough; and

8                   a fiber optic scope extending through said  
9 third lumen.

10                  57. The catheter system of Claim 35 wherein at  
11 least a portion of said shaft surrounding said drug  
12 delivery lumen is formed of a low compliance material so  
13 that flow control at said distal drug delivery orifice of  
14 a fluid delivered through said drug delivery lumen is  
15 more responsive to flow control at a location proximal  
16 thereto.

17                  58. The catheter system of Claim 35 further  
18 comprising:

19                  a vibrating material located close to said  
20 distal orifices.

21                  59. The catheter system of Claim 58 in which  
22 said vibrating material is a piezoelectric material and  
23 further in which said piezoelectric material is connected  
24 to at least one electrical conductor that extends through  
25 said catheter shaft.

26                  60. A suction catheter for use with an  
27 endotracheal tube, said suction catheter sized to be  
28 received in a ventilation lumen of the endotracheal tube,  
29 said suction catheter having an aspiration lumen for  
30 removing mucous from the respiratory tract of an  
31 intubated patient, said suction catheter further  
32 including:

1           a gas pressurization lumen extending through a  
2 wall of said suction catheter adjacent to said aspiration  
3 lumen;

4           a distal gas exit orifice communicating with  
5 said gas pressurization lumen, said distal gas exit  
6 orifice located at the distal end of said suction  
7 catheter;

8           a drug delivery lumen extending through the  
9 wall of said suction catheter adjacent to said aspiration  
10 lumen;

11           a distal drug delivery orifice communicating  
12 with said drug delivery channel, said distal drug  
13 delivery orifice located in proximity to the distal gas  
14 exit orifice so that gas exiting from said distal gas  
15 exit orifice nebulizes a drug delivered from said distal  
16 drug delivery orifice.

17           61. The suction catheter of Claim 60 in which  
18 said distal gas exit orifice and distal drug delivery  
19 orifice are oriented proximally toward a distal suction  
20 opening communicating with said aspiration lumen.

21           62. The suction catheter of Claim 60 in which  
22 said distal gas exit orifice and distal drug delivery  
23 orifice are oriented radially relative to an axis of said  
24 suction catheter.

25           63. A method of forming a catheter for  
26 nebulizing a liquid with a gas, the catheter having  
27 closely spaced distal orifices sized and spaced apart  
28 with low tolerances, comprising the steps of:

29           providing a relatively large size multilumen  
30 extruded polymer tubing;

31           heating a portion of the tubing to a transition  
32 temperature of said tubing;

33           drawing down said portion of tubing to form a  
34 tapered section with a draw down ratio in the range

1       between 2 to 1 and 20 to 1 such that the lumens are  
2       increasingly closely spaced in said tapered region; and  
3               forming a plurality of orifices at a distal end  
4       of said tapered section, said plurality of orifices being  
5       sized to nebulize a liquid delivered through one of said  
6       lumens to form an aerosol with a gas delivered through  
7       another of said lumens.

8               64. The method of Claim 63 the which the step  
9       of forming a plurality of orifices further comprises:  
10              cutting a distal end of the tapered section.

11             65. The method of Claim 63 further comprising:  
12             cutting the tubing to size to form a shaft  
13       portion of the nebulization catheter.

14             66. The method of Claim 63 further comprising:  
15             exposing a portion of said tubing to high  
16       energy radiation.

17             67. The method of Claim 63 in which said  
18       catheter is for use in the respiratory system.

19             68. The method of Claim 63 in which the step  
20       of heating further comprises:  
21             heating the tubing to a temperature between a  
22       melt state and a glass state of said tubing.